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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/623,864

07/22/2003

Dietrich Wilhelm Schacht

25348

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7590

12/07/2006

NATH & ASSOCIATES

112 South West Street
Alexandria, VA 22314

EXAMINER

RAE, CHARLESWORTH E

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 12/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/623,864

Applicant(s)

SCHACHT ET AL.

Examiner

Charlesworth Rae

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-7 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

Claims 1-7 are currently pending and are the subject of this Office Action.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-6, drawn to a transdermal delivery system (TDS), classified in class 424, subclass 448. If this Group is elected, then the below summarized Species Election is also required.
- II. Claim 7, drawn to a method for treatment of a patient suffering from a disease treatable by rotigotine by applying the TDS according to claim 1 to the skin of the patient, classified in class 514, subclass 438. If this Group is elected, then the below summarized Species Election is also required.

Inventions I and II are related as product and process of use in that invention I is directed towards a transdermal delivery system (TDS), while invention II is directed towards a method of using the TDS for treatment of a patient suffering from a disease treatable by rotigotine. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the inventions as claimed are distinct because the inventions are either not capable of use together or can have a materially different design, mode of operation, function in view of their divergent subject matter.

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Specifically, invention II as claimed can be practiced with another materially different product, for example, clonidine, for treating patients with hypertension.

Because inventions I and II are independent or distinct for the reasons given above coupled with the fact that a search is required for each group, restriction for examination purposes is proper. While Groups I and II can be identically classified under U.S. Patent Classification guidelines, to search them together would present an undue search burden on the Examiner due to the extensive databases of patent and non-patent literature that would have to be searched in view of the divergent subject matter encompassed by the different groups. Additionally, each invention has acquired a different status in the relevant art. Thus, Groups I and II have been appropriately restricted on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

Election of Species regarding Groups I and II

This application contains claims directed to more than one species of the generic Inventions that would require an unduly extensive and burdensome search by the examiner if all the claimed species were examined together.

For example, inventions I and II encompass multiple species of the self-adhesive matrix solid semi-permeable polymer or semi-solid semi-permeable polymer system; namely, a) silicone-type sensitive adhesive, and b) acrylate (see Specification, page 2, lines 2 to 4). Please be cautioned that claims to any specific self-adhesive matrix polymer system not specifically disclosed in the instant specification as originally filed may result in a New Matter rejection.

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If applicant elects a silicone-type sensitive adhesive, then applicant is further required to elect a sub-specie from the following list of silicone-type sensitive adhesive:

- 1) single silicone type pressure sensitive adhesive as the main adhesive compound, or
- 2) multiple (i.e. two or more) silicone type pressure sensitive adhesives as the main adhesive compounds.

Each specie exhibits a different pharmaceutical characteristic, which would necessarily confer a different pharmacokinetic property to the transdermal delivery system. The species are therefore independent or distinct because they represent different physical characteristics. In view of the undue search burden that will be created by the different pharmaceutical characteristic of the above species, applicant is required to elect either a) a single silicone type pressure sensitive adhesive, or b) a multiple (i.e. two or more) silicone type pressure sensitive adhesives, for purposes of examination. Please be cautioned that claims to any specific self-adhesive matrix polymer system not specifically disclosed in the instant specification as originally filed may result in a New Matter rejection.

Additional Election of Species regarding Groups I and II

This application also contains claims directed to more than one species of silicone "tack" of the generic inventions that would require an unduly extensive and burdensome search by the examiner if all the claimed species were examined together. For example, inventions I and II encompass the following species of silicone tack:

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1) blend of a high tack silicone comprising polysiloxane with a resin and a medium tack silicone type pressure sensitive adhesive comprising polysiloxane with a resin, or

2) a high tack silicone comprising polysiloxane with a resin, or

3) a medium tack silicone type pressure sensitive adhesive comprising polysiloxane with a resin.

Each specie exhibits a different pharmaceutical characteristic, which would necessarily confer a different pharmacokinetic property to the transdermal delivery system. The species are therefore independent or distinct because they represent different physical characteristics. In view of the undue search burden that will be created by the different physical characteristic of the single versus multiple silicone type pressure sensitive adhesives encompassed by these claims, applicant is required to elect a specie of silicone tack from the above species list i.e. 1) blend of high and medium tack, or 2) high tack, or 3) medium tack, for purposes of examination.

The divergent subject matter, coupled with the fact that the species have acquired a different status in the art, creates a search burden on the examiner. In view of the undue search burden that will be created by the multiplicity of tumor, viral, and bacterial cells encompassed by these claims, applicant is required to elect one single cell species for examination purposes and provide justification for the election with respect to differences in structure, function, and method of using as appropriate. Please be cautioned that claims to any specific self-adhesive matrix polymer system not

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specifically disclosed in the instant specification as originally filed may result in a New Matter rejection.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 27, 28, 29, 30, 31, 38, 39, 42, 43, and 44 are considered generic to the above listed species.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

Inventorship Notice

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charlesworth Rae whose telephone number is 571-272-

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6029. The examiner can normally be reached between 9 a.m. to 5:30 p.m. Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http:pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 800-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

1 December 2006
CER


ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER